

### **III. Remarks**

#### **A. Amendments to the Claims**

The independent claims 46, 64 and 67 have been amended to recite a preferred embodiment of the invention that the claimed antimicrobial composition consists exclusively of generally recognized as safe flavoring agents. Support for the amendment is provided in the Specification at page 11, lines 24–28 and by claim 61.

Claim 61 has been canceled.

#### **B. Rejection of Claims Under 35 U.S.C. Section 103**

Claims 46, 57, 58, 61, 63, 64 and 66–70 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of United States Patent No. 5,750,563 to Honda, in view of United States Patent No. 5,322,689 to Hughes et al. and United States Patent No. 5,416,075 to Carson et al.

##### **1. The Examiner's reasons for the rejection**

The Examiner's reasons for the rejection apply to Applicant's claimed composition before the amendment. They are not repeated here.

The Examiner's "Response to [Applicant's] Arguments" remains very pertinent to the rejection and is set forth herebelow.

Applicant's arguments filed 1/11/08 have been fully considered but they are not persuasive. Applicant argues that:

a. Since the kojic acid required by the '563 patent is not GRAS, it changes the fundamental properties of the composition and, therefor does not obviate the claims.

b. None of the patents teach or obviate the instant invention since they do not disclose an antimicrobial formulation comprising a polyphenols [*sic*] and no other flavoring alcohols.

Regarding argument a., although kojic acid is not GRAS that does not preclude it from being included into the formulation. The instant invention is *not* GRAS; it merely cannot comprise any other GRAS compounds. That does not make the *entire* composition GRAS. The instant invention is recited to antimicrobial, and it achieved this property by the presence of the polyphenols compounds in preferred concentrations. The '563 patent provides compositions comprising tannic acid derivatives (claim 1). These compounds are present in an amount from 01–20% within the limits of the instant claims and sufficient to provide an antimicrobial effect. Applicant argues that kojic acid is [not] GRAS; however the compound is used in food preservation such as seafood to preserve the pink color or to stop the discoloration of cut fruit. As such the compound is safe for human consumption and would be useful in perishable products such as those recited in claim 66. This compound would not change the fundamental properties of the composition and therefor the '563 composition in combination with the '689 patent would continue to obviate the claims.

Regarding argument b., it remains the position of the Examiner that the combination of the '563 and '689 patent[s] would provide an obviating composition, that meets all of the limitations of the instant claims. The '563 patent discloses a composition comprising kojic acid and tannic acid derivative, along with optional humectant and emollients. These emollients are well known in the art and can be seen in the '689 patent. The '689 patent provides a composition comprising antibiotics and carriers such as lactic acid (col. 7, lin. 3–68). Benzyl alcohol is only listed in the alternative and is not a required component. The patent establishes the level of skill in the art regarding lactic acid and its use as a carrier compound. Also the lactic acid is present in a concentration within the limits of the instant claims. It would have been obvious to include the lactic acid compounds of the '689 patent into the preservative compound of the '563 patent in order to provide a stable formulation. For these reasons the claims remain obviated.

(Examiner's Action, page 5, line 3, to page 6, line 13).

Because the Examiner appears to argue that claim 65 is also rejected, Applicant's reply to the Examiner's Action includes claim 65. (See Examiner's Action at page 4, lines 4–8).

**2.     Legal standard for rejections under 35 U.S.C. Section 103**

The legal interpretation of Section 103 to be applied is set forth in the recent Supreme Court decision of *KSR International Co. v. Teleflex Inc. (KSR)*, 550 U.S. \_\_\_, 82 USPQ2d 1385 (2007). *KSR* cites *Graham v. John Deere Co. of Kansas City*, (383 U.S. 1, 17–18 [148 USPQ 459] (1966)) as setting out an objective analysis for applying Section 103. (82 USPQ2d at 1388). The objective analysis is as follows:

Under § 103, the scope and content of the prior art are to be determined; the differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background, the obviousness or nonobviousness of the subject matter is determined. Such secondary considerations as commercial success, long felt but unsolved needs, failure of others, *etc.*, might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented. As indicia of obviousness or nonobviousness, these inquiries may have relevancy.

(148 USPQ at 467).

Accordingly, the factual inquiries set forth by the Court are as follows:

- [T]he scope and content of the prior art are . . . determined;
- Differences between the prior art and the claims at issue are . . . ascertained;
- The level of ordinary skill in the pertinent art [is] resolved; and
- Such secondary considerations as commercial success, long felt but unsolved needs, failure of others, *etc.*, might be utilized. . . .

**3. Application of the *Graham v. John Deere Co.* factual standards**

**a. Determining the scope and content of the prior art**

The Honda patent is directed to a preparation for epidermis containing kojic acid and/or its derivative and at least one member selected from the group consisting of alcohols and polyphenols (See '563 patent, Abstract and Summary of the Invention at Column 2, lines 15–24). Kojic acid is defined as 5-hydroxy-2-hydroxymethyl-pyrone (Column 2, lines 32–33).

Honda requires the presence of kojic acid, which is the essential ingredient of the preparation disclosed by Honda. Honda is concerned with a technique of kojic acid preparation that provides the preparation “with enough stability to stand severe distributive machinery without giving unpleasant feeling upon application thereof to the skin” (Column 1, lines 38–43).

Hughes et al. is directed to a topical oil-in-water emulsion composition useful for releasing an aromatic decongestant composition comprising a carboxylic copolymer and volatile aromatic compounds (Column 2, lines 26–54). Hughes et al. describes as optional components pharmaceutical actives such as benzyl alcohol (which is excluded from Applicant's claimed antimicrobial composition), as well as humectants/moisturizers. (See column 6, line 12, to column 9, line 61). In Hughes et al., lactic acid is identified as one of a number of humectants and moisturizers and is not disclosed as a preferred humectant/moisturizer for use in the compositions of the Hughes et al. invention. (See column 7, lines 39–59). Hughes et al. does not exemplify, disclose or even suggest to one of ordinary skill in the art the exclusion from the Hughes et al. composition of benzyl alcohol and other generally recognized as safe flavored alcohols, other than polyphenol.

Carson et al. is relied on as disclosing antimicrobial emulsions comprising extracts and antimicrobial compounds. The extracts are identified as including essential oils, including camphor, orange oil and anise oil (Examiner's Action, page 4, lines 9–11). Carson et al. does not disclose Applicant's claimed antimicrobial composition consisting essentially of a mixture free of benzyl alcohol, containing from 0.1 to 90% by weight of a polyphenol selected from the group consisting of tannins and tannic acid, 0.1 to 30% by weight of lactic acid, and that the mixture contains no other generally recognized as safe flavored alcohols.

**b.     **Ascertaining the differences  
between the prior art and the claims at issue****

Applicant's independent claims 46, 64 and 67 are now directed to an antimicrobial composition that consists exclusively of generally recognized as safe flavoring agents. The compositions consist essentially of and are in the form of a mixture of 0.1 to 90% by weight of a polyphenol selected from the group consisting of tannins and tannic acid and 0.1% to 30% by weight of lactic acid. The mixture contains no other generally recognized as safe flavored alcohols and is free of benzyl alcohol.

The remaining claims 57–58, 63, 65–66 and 68–70 are dependent upon claims 46, 64 or 67 or upon a claim that is dependent ultimately upon one of claims 46, 64 or 67.

As noted above, Honda requires the presence of kojic acid, which is an essential ingredient of the Honda preparation. In the "Response to Arguments" quoted hereabove, the Examiner contended that although kojic acid is not GRAS, that fact did not preclude the inclusion of kojic acid in Applicant's claimed antimicrobial composition because the entire claimed composition is not GRAS.

Applicant's claimed composition now consists exclusively of generally recognized as safe (*i.e.*, GRAS) flavoring agents. Accordingly, kojic acid cannot be included in Applicant's claimed composition.

The Examiner also observed that kojic acid is used in food preservation such as seafood and concludes that the compound is safe for human consumption (Examiner's Action at page 5, lines 18-21). Applicant respectfully disagrees that kojic acid can be assumed to be as safe for human consumption as generally recognized as safe flavoring agents. As disclosed in the Specification at page 6, lines 1-9:

The GRAS flavoring agents in the mixtures (A) and (B) are recognized by the FDA authority as commercially safe for use in foods (GRAS = generally recognized as safe in food). The mentioned GRAS flavor alcohols and GRAS flavoring agents are the compounds mentioned in the FEMA/FDA GRAS Flavour Substances Lists GRAS 3-15 No. 2001-3815 (as of 1997). This list contains natural and synthetic flavoring agents approved by the American public health authority, FDA, for use in foods (FDA Regulation 21 CFR 172.515 (Synthetic Flavoring Substances and Adjuvants) and FDA Regulation 21 CFR 181.20 (Natural Flavoring Substances and Adjuvants)).

Kojic acid is not certified by the Food and Drug Administration as generally recognized as safe in foods. The *Wikipedia* definition of "kojic acid" includes as an External link "Safety MSDS data." That data includes the statement under the heading "Toxicology," "May be harmful by inhalation, ingestion and if absorbed through skin. Irritant." Copies of the *Wikipedia* definition and the safety data sheet are attached as **EXHIBIT A**. If kojic acid is harmful for ingestion, kojuc acid cannot be construed as equivalent to a generally recognized as safe compound. As noted above, Honda acknowledges that kojic acid must be handled by a special technique to avoid "giving unpleasant feeling upon application to the skin" (Column 1, lines 38-43).

Accordingly, Applicant's claimed antimicrobial composition excludes an essential ingredient in the Honda preparation that is not an equivalent to Applicant's generally recognized as safe flavoring agents.

As noted above, Hughes et al. is directed to a topical oil and water emulsion composition useful for releasing an aromatic decongestant composition comprising a carboxylic copolymer and volatile aromatic compounds. Hughes et al. also does not disclose or suggest to one of ordinary skill in the art Applicant's claimed antimicrobial composition that consists exclusively of generally recognized as safe flavoring agents.

Carson et al. is relied on by the Examiner as disclosing antimicrobial emulsions comprising extracts (*i.e.*, essential oils including camphor orange oil and anise) and antimicrobial compounds. (Examiner's Action at page 4, lines 9–11). Carson et al. also does not disclose or suggest to one of ordinary skill in the art Applicant's claimed antimicrobial composition that consists exclusively of generally recognized as safe flavoring agents.

**c. Resolving level of ordinary skill in the pertinent art**

The inventor of the present application and the inventors of the prior art patents would represent persons of ordinary skill in the art.

**d. Secondary considerations**

There has been a long felt but unsolved need for Applicant's claimed antimicrobial compositions, which act as a food preservative and are formed entirely from generally recognized as safe flavoring agents.

**4. Applicant's claimed invention is unobvious**

As noted above, none of the prior art relied on in the rejection of the claims discloses or suggests to one of ordinary skill in the art Applicant's claimed antimicrobial composition that consists exclusively of generally recognized as safe flavoring agents. Instead, Honda discloses a preparation that has as an essential ingredient, kojic acid, which is not a generally recognized as safe flavoring agent. Combining Honda with Hughes et al. and Carson et al. would result in a composition comprising kojic acid as there is no suggestion in Hughes et al. and Carson et al. to exclude kojic acid from their compositions. Therefore, the Honda, Hughes et al. and Carson et al. disclosures cannot be combined by one of ordinary skill in the art to obtain Applicant's claimed antimicrobial composition.

Accordingly, for the reasons set forth above, the rejection of claims 46, 57, 58, and 63-70 under 35 U.S.C. Section 103(a) as being unpatentable over the combined disclosures of United States Patent No. 5,750,563 to Honda, in view of United States Patent No. 5,322,689 to Hughes et al. and United States Patent No. 5,416,075 to Carson et al. is untenable and should be withdrawn.



**IV. Conclusion**

It is believed that the above Amendment and Remarks constitute a complete Response under 37 C.F.R. § 1.111 and that all grounds for objection stated in the Examiner's Action have been adequately rebutted or overcome. A Notice of Allowance in the next Examiner's Action is therefore requested. The Examiner is requested to telephone the undersigned counsel if any matter that can be expected to be resolved in a telephone interview is believed to impede the allowance of pending claims 46, 57-58 and 63-70 of Application Serial No. 09/743,883.

Respectfully submitted,

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